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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/617,456	07/11/2003	Mongkol Sriwongjanya	141-287	3239

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EXAMINER	
TRAN, SUSAN T	
ART UNIT	PAPER NUMBER
1615	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/09/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/617,456	SRIWONGJANYA ET AL.	
	Examiner	Art Unit	
	Susan T. Tran	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 December 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-49 and 51-64* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-49 and 51-64* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 20-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 20 is rejected for failing to further limit the subject matter of claim 1. Claim 1 has already recited the limitation "channeling agent".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 3-6, 8, 9, 12, 13, 17-20, 27, 28, 30-32 and 64 are rejected under 35 U.S.C. 102(e) as being anticipated by Chen et al. USPN 7,022,342.

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome

either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Chen discloses an oral controlled release capsule comprising: 1) a core comprising a β-adrenergic blocking agent, an inert pellet, a binder, and a filler; and 2) a coating comprising a water-insoluble polymer, a water soluble polymer, a plasticizer, and an anti-sticking agent (column 1, lines 8-18; and column 3, lines 6-30). β-adrenergic blocking agent includes metoprolol. Inert pellet as a starting material can be any type of commonly known pellet including starch or sugar sphere having diameter from about 15-50 mesh. Binder includes hydroxypropyl methylcellulose (column 4, lines 16-42). Water-insoluble polymer includes cellulose acetate butyrate. Plasticizing agent includes well-known pharmaceutically acceptable agents (column 5, lines 10-56). Chen further discloses the process for preparing the oral controlled release dosage form comprising forming a suspension of the binder, drug and other ingredients, layering the suspension onto the inert pellet using any of the layering techniques known in the art such as fluidized bed coating, rotor granulation or pan coating, and layering the controlled release coating layer by any means commonly known in the art (column 5, lines 3-9, and 57-64). The claimed release profiles, as well as the C_{max} values are disclosed in columns 6 and 9.

It is noted that independent claims 1 and 49 require channeling agent. However, the specific channeling agent is not recited in these claims. Therefore, any other

additives/excipients such as filler having particle size of about 20 μm anticipated the claimed channeling agent (column 4, lines 48-51).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 3-6, 8, 9, 12, 13, 17-23, 27-49, 51-54, 56, 57 and 60-64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al. USPN 7,022,342, in view of Sriwongjanya et al. WO 99/61005.

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer

in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Chen is relied upon for the reason stated above. Chen does not teach the channeling agent in the controlled release coating layer.

Sriwongjanya teaches a controlled release oral dosage in the form of tablet or pellet comprising an active core, and a controlled release coating layer comprising channeling agent such as methacrylic acid copolymer (page 8, lines 5-19). The dosage form further comprises an immediate release tablet or pellet containing active drug. The controlled release and immediate release tablets or pellets are placed in a hard gelatin capsule for administration to animal or human (page 5, lines 4-10; and page 10, lines 6-9). Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the controlled release dosage of Chen to include the immediate release dosage form and the channeling agent in view of the teachings of Sriwongjanya, because Sriwongjanya teaches channeling agent increases the volume of fluid imbibed into the core and creates channels to enable the dosage form to dispense the drug (page 8, lines 7-9), because Sriwongjanya teaches a controlled release dosage form that is easy to manufacture and can be used to prepare a range of dosing levels, because Sriwongjanya teaches a controlled release dosage form having similar C_{max} value and release profile as desired by Chen (page 3, lines 21-27), and because Chen teaches the desirability to obtain a controlled release dosage form characterized by a high extent of absorption, and a high bioavailability that can provide

therapeutic levels of the drug to a subject in need of such treatment over a twelve to twenty-four hour period (column 2, lines 59-67).

Claims 7, 10, 11, 14-16, 24-26, 49, 55, 58 and 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al. USPN 7,022,342, in view of Patel et al. US 6,569,463.

Chen is relied upon for the reasons stated above. Chen does not teach the claimed surfactant in the core composition.

Patel teaches a solid pharmaceutical composition comprising a solid carrier including a substrate and an encapsulation coat comprising active drugs and surfactants (abstract). Surfactant includes tween 80 (polysorbate 80) (tablet 11 at column 19, line 12). The substrate includes pellet, bead, or the like such as sugar or microcrystalline cellulose (column 28, lines 20-40). The solid carrier is further coated with a delayed release coating comprising an enteric polymer, plasticizer, and surfactant (column 34, lines 38-50; and column 35, lines 1-67). Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the controlled release dosage of Chen to include the surfactant in view of the teaching of Patel, because Patel teaches using surfactant to increase solubility, improve dissolution, enhance absorption and bioavailability of the active ingredient in the solid carrier (column 9, lines 63 through column 10, lines 1-17), because Patel teaches a dosage form suitable for metoprolol (column 8, line 31), and because Chen teaches the

desirability to obtain a controlled release dosage form characterized by a high extent of absorption, and a high bioavailability (column 2, lines 59-67).

It is noted that the cited references do not explicitly teach the claimed inert core diameter of about 60-80 mesh. However, it would have been obvious to one of ordinary skill in the art to, by routine experimentation optimize the inert core size to obtain the claimed invention, because Chen teaches an inert core having size of about 50 mesh, and because Patel teaches any pharmaceutically known inert core.

Claims 1, 3-9, 14-49, 51-57 and 60-64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stark et al. US 6,733,789, in view of Busetti et al. US 6,190,692 and Sriwongjanya et al. WO 99/61005.

Stark teaches a multiparticulate formulation comprising an inert core coated with active drug in the present of binder and other additives (column 3, lines 45-56). The coated core is further coated with a polymeric coating layer comprising combination/mixture of water-insoluble polymer including cellulose acetate butyrate (column 3, lines 58 through column 4, lines 1-9). The polymeric coating layer further comprises methacrylic acid copolymer (column 4, lines 54-63), one ore more soluble excipients including polysorbate, poloxamers, and plasticizer (column 5, lines 54 through column 6, lines 1-36). Stark also teaches the claimed release profile, wherein 0-10% of the active agent is released after 2 hours, less than 50% is released after 4 hours, and greater than 20% is released after 10 hours (column 3, lines 1-20; and table 1). Stark further teaches the multiparticulate can be formulated into tablet or capsule for

oral administration (column 7, lines 4-14). The process for preparing the multiparticulate is disclosed in column 3, lines 45-56; column 6, lines 43-56; and examples).

Stark does not specifically teach the claimed combination of polymers, which include the claimed channeling agent.

Sriwongjanya teaches a controlled release oral dosage in the form of tablet or pellet comprising an active core, and a controlled release coating layer comprising channeling agent such as methacrylic acid copolymer (page 8, lines 5-19). The dosage form further comprises an immediate release tablet or pellet containing active drug. The controlled release and immediate release tablets or pellets are placed in a hard gelatin capsule for administration to animal or human (page 5, lines 4-10; and page 10, lines 6-9). Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the controlled release dosage of Stark to include the channeling agent in view of the teachings of Sriwongjanya, because Sriwongjanya teaches channeling agent to increase the volume of fluid imbibed into the core and create channels to enable the dosage form to dispense the drug (page 8, lines 7-9), because Sriwongjanya teaches a controlled release dosage form that is easy to manufacture and can be used to prepare a range of dosing levels, and because Stark teaches combination of polymers in the controlled release coating layer.

Stark does not expressly teach the claimed active drug.

Busetti teaches a controlled release formulation comprising drug includes β-blocker such as bisoprolol and metoprolol succinate (column 4, lines 40-46). Thus, it

would have been obvious to one of ordinary skill in the art to prepare a multiparticulate formulation according to Stark to deliver metoprolol, because Busetti teaches β-blocker such as metoprolol is known in the art, because Busetti teaches the equivalency between bisoprolol and metoprolol, and because Stark teaches a formulation suitable for the delivery of β-blocker active agents.

It is noted that Stark does not explicitly teach the claimed inert core diameter of about 60-80 mesh. However, it would have been obvious to one of ordinary skill in the art to, by routine experimentation optimize the inert core size to obtain the claimed invention, because Stark teaches the use of any pharmaceutically known inert core having size ranges from 0.4-1.1 mm (column 3, lines 42-44).

Claims 10-16, 58 and 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stark et al. US 6,733,789, in view of Busetti et al. US 6,190,692 and Patel et al. US 6,569,463.

Stark is relied upon for the reason stated above. Stark does not teach the core composed of swellable material such as microcrystalline cellulose.

Patel teaches a solid pharmaceutical composition comprising a solid substrate encapsulated with active drugs and surfactants (abstract). Surfactant includes tween 80 (polysorbate 80) (tablet 11 at column 19, line 12). The substrate includes nonpareil or microcrystalline cellulose (column 28, lines 20-40). Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to select microcrystalline cellulose as an inert carrier in view of the teaching of Patel, because

Patel teaches nonpareil seed and microcrystalline cellulose core are well known in pharmaceutical art as an inert carrier, and because Stark teaches the use of any known inert carrier.

Response to Arguments

Applicant's arguments filed 12/18/06 have been fully considered but they are not persuasive.

Applicant indicates that Chen reference is not qualify as prior art because it is owned by the same entity as the present application.

However, in order to be disqualified as prior art under 35 U.S.C. 103(c), the subject matter which would otherwise be prior art to the claimed invention and the claimed invention must be commonly owned, or subject to an obligation of assignment to a same person, at the time the claimed invention was made. See MPEP § 706.02(l) for 35 U.S.C. There must be a statement that the common ownership was "at the time the invention was made."

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-F 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

S. Tran
Patent Examiner
Art Unit 1615